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09/530,361	04/28/2000	GUIDO MORUZZI	027650-857	5394

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EXAMINER	
CHORBAJI, MONZER R	
ART UNIT	**PAPER NUMBER**
1744	

DATE MAILED: 10/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/530,361	MORUZZI, GUIDO	
	Examiner	Art Unit	
	MONZER R. CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6,15,17,18 and 21-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6,15,17,18 and 21-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 April 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This final action is in response to the amendment received on 08/19/2005

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 4 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kodera et al (U.S.P.N. 4,366,125) in view of DiGeronimo (U.S.P.N. 4,494,357) and further in view of Loliger et al (U.S.P.N. 3,692,468).

With respect to claim 4, the Kodera reference teaches a method for sterilizing a packaging sheet material (col.1, lines 8-13) including the following: applying a liquid solution of hydrogen peroxide to the surface of a packaging by immersing the material in a hydrogen peroxide bath (col.6, lines 25-28) at a certain temperature (col.4, lines 23-25), which includes microorganisms, applying a stream of air the packaging sheet material for removing a substantial amount of hydrogen peroxide from the surface of the

packaging material (col.5, lines 10-15), irradiating the surface with UV light at a certain wavelength value (figure 1, C) and immersing for the material for one second (col.6, lines 25-28 and lines 36-39). The specification only teaches of microorganisms without providing any significance. As a result, the microorganisms present on the surfaces of the packaging sheet material in the Kodera reference intrinsically absorb the residual hydrogen peroxide left after the step of drying. In addition, the Kodera reference teaches the importance of the synergistic effect produced by the combination of hydrogen peroxide and UV (col.1, lines 13-18). Clearly the Kodera process provides for a trace quantity of hydrogen peroxide for its interaction with the UV light. However, the Kodera reference fails to explicitly disclose a wavelength range value for the UV light and a temperature range value for the hydrogen peroxide bath. The DiGeronimo reference, which is in the art of sterilizing packaging material, teaches irradiating at 254 nm (col.2, lines 50-52). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Kodera reference by irradiating at 254 nm as taught by the DiGeronimo reference since the lamp at such a wavelength operates at 99.9% efficiency (col.2, lines 50-52).

With respect to claim 4, the DiGeronimo reference fails to disclose a temperature range value for the hydrogen peroxide bath, but the Loliger reference, which is in the art of sterilizing packaging material, teaches maintaining the hydrogen peroxide bath temperature at 60 degree Celsius (col.2, lines 70-71). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Kodera reference by heating the hydrogen peroxide bath to 60

degree Celsius as taught by the Loliger reference since it is known in the art that at such a temperature packing sheet residence time in the bath is only 6 second that even kills heat-resistant germs (col.1, lines 30-33).

With respect to claim 28, the Kodera reference teaches a method for sterilizing a packaging sheet material (col.1, lines 8-13) including the following: applying a liquid solution of hydrogen peroxide to the surface of a packaging by immersing the material in a hydrogen peroxide bath (col.6, lines 25-28) at a certain temperature (col.4, lines 23-25), which includes microorganisms, applying a stream of air the packaging sheet material for removing a substantial amount of hydrogen peroxide from the surface of the packaging material (col.5, lines 10-15), irradiating the surface with UV light at a certain wavelength value (figure 1, C), immersing for the material for one second (col.6, lines 25-28 and lines 36-39) and the packaging sheet material is intrinsically hydrophobic. The specification only teaches of microorganisms without providing any significance. As a result, the microorganisms present on the surfaces of the packaging sheet material in the Kodera reference intrinsically absorb the residual hydrogen peroxide left after the step of drying. In addition, the Kodera reference teaches the importance of the synergistic effect produced by the combination of hydrogen peroxide and UV (col.1, lines 13-18). Clearly the Kodera process provides for a trace quantity of hydrogen peroxide for its interaction with the UV light. However, with respect to claim 28, the Kodera reference fails to explicitly disclose a wavelength range value for the UV light, a temperature range value for the hydrogen peroxide bath and a temperature value range for the drying air. The DiGeronimo reference, which is in the art of sterilizing packaging

material, teaches irradiating at 254 nm (col.2, lines 50-52) and a temperature value range for the drying air (col.3, lines 13-14). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Kodera reference by irradiating at 254 nm as taught by the DiGeronimo reference since the lamp at such a wavelength operates at 99.9% efficiency (col.2, lines 50-52).

With respect to claim 28, the DiGeronimo reference fails to disclose a temperature range value for the hydrogen peroxide bath, but the Loliger reference, which is in the art of sterilizing packaging material, teaches maintaining the hydrogen peroxide bath temperature at 60 degree Celsius (col.2, lines 70-71). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Kodera reference by heating the hydrogen peroxide bath to 60 degree Celsius as taught by the Loliger reference since it is known in the art that at such a temperature packing sheet residence time in the bath is only 6 second that even kills heat-resistant germs (col.1, lines 30-33).

4. Claims 2-3, 5, 15, 17 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kodera et al (U.S.P.N. 4,366,125) in view of DiGeronimo (U.S.P.N. 4,494,357).

With respect to claims 15, 21, 23 and 26, the Kodera reference teaches a method and an apparatus (figure 1) for sterilizing a packaging sheet material (col.1, lines 8-13) including the following: applying a liquid solution of hydrogen peroxide to the surface of a packaging by advancing (figure 1, 3) the material into a hydrogen peroxide

bath for immersing (means for applying) the material into a hydrogen peroxide bath (col.6, lines 25-28), which includes microorganisms, applying a stream of hot air (figure 1, 42) the packaging sheet material for removing a substantial amount of hydrogen peroxide from the surface of the packaging material (col.5, lines 10-15), irradiating the surface with UV light (figure 1, 34) at a certain wavelength value (figure 1, C) by directing UV light onto the surface of the material (figure 1, 34 and 1), the packaging sheet material is intrinsically hydrophobic and means for advancing the packaging sheet material (figure 1, 3).The specification only teaches of microorganisms without providing any significance. As a result, the microorganisms present on the surfaces of the packaging sheet material in the Kodera reference intrinsically absorb the residual hydrogen peroxide left after the step of drying. In addition, the Kodera reference teaches the importance of the synergistic effect produced by the combination of hydrogen peroxide and UV (col.1, lines 13-18). Clearly the Kodera process and apparatus provide for a trace quantity of hydrogen peroxide for its interaction with the UV light. In addition, with respect to claim 15, the Kodera reference discloses the use of tank for immersing the packaging sheet in liquid hydrogen peroxide without providing its intrinsic depth measurements; however, determining the proper depth depends on the dimensions of the thickness of the packaging material, i.e., very thick laminates require a deeper bath. This is an obvious matter of choice of design within the scope of the artisan. With respect to claims 15, 21, 23 and 26, the Kodera reference fails to explicitly disclose a wavelength range value for the UV light, but the DiGeronimo reference, which is in the art of sterilizing packaging material, teaches irradiating at 254 nm (col.2,

lines 50-52). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Kodera reference by irradiating at 254 nm as taught by the DiGeronimo reference since the lamp at such a wavelength operates at 99.9% efficiency (col.2, lines 50-52).

With respect to claims 5 and 22, the Kodera reference teaches a method for sterilizing a packaging sheet material (col.1, lines 8-13) including the following: applying a liquid solution of hydrogen peroxide to the surface of a packaging by advancing (figure 1, 3) the material into a hydrogen peroxide bath for immersing the material into a hydrogen peroxide bath (col.6, lines 25-28), which includes microorganisms, applying a stream of hot air (figure 1, 42) onto the packaging sheet material for removing a substantial amount of hydrogen peroxide from the surface of the packaging material (col.5, lines 10-15), irradiating the surface with UV light (figure 1, 34) at a certain wavelength value (figure 1, C) by directing UV light onto the surface of the material (figure 1, 34 and 1), the packaging sheet material is intrinsically hydrophobic. The specification only teaches of microorganisms without providing any significance. As a result, the microorganisms present on the surfaces of the packaging sheet material in the Kodera reference intrinsically absorb the residual hydrogen peroxide left after the step of drying. In addition, the Kodera reference teaches the importance of the synergistic effect produced by the combination of hydrogen peroxide and UV (col.1, lines 13-18). Clearly the Kodera process and apparatus provide for a trace quantity of hydrogen peroxide for its interaction with the UV light. However, with respect to claims 55 and 22, the Kodera reference fails to explicitly disclose the following: a wavelength

range value for the UV light, a concentration of at least 10% by weight and a temperature value range for the drying air. The DiGeronimo reference, which is in the art of sterilizing packaging material, teaches the following: irradiating at 254 nm (col.2, lines 50-52), a concentration of at least 10% by weight (the DiGeronimo reference teaches in col.3, lines 10-11, that a 30% hydrogen peroxide solution is used without specifying whether the percentage is weight or volume. However, assuming a 100 ml of solution and using the density of hydrogen peroxide, a 30 ml of hydrogen peroxide corresponds to 42.2 g of hydrogen peroxide, which is equivalent to 38 percent by weight) and a temperature value range for the drying air (col.3, lines 13-14). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Kodera reference by irradiating at 254 nm as taught by the DiGeronimo reference since the lamp at such a wavelength operates at 99.9% efficiency (col.2, lines 50-52).

With respect to claims 2-3 and 24, the Kodera reference disclose hydrogen peroxide bath concentration of 5% (col.6, lines 8-10), but fails to teach hydrogen peroxide concentration of up to 50% or between 20% to 40%; however, the DiGeronimo reference teaches in col.3, lines 10-11, that a 30% hydrogen peroxide solution is used without specifying whether the percentage is weight or volume. However, assuming a 100 ml of solution and using the density of hydrogen peroxide, a 30 ml of hydrogen peroxide corresponds to 42.2 g of hydrogen peroxide, which is equivalent to 38 percent by weight. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Kodera reference by

optimizing the hydrogen peroxide concentration since such a modification is a matter of routine experimentation that depends on how much the packaging sheet material is contaminated with microorganisms, for example, heavily contaminated material requires higher concentration values for hydrogen peroxide.

With respect to claim 17, the Kodera reference fails to explicitly disclose a wavelength range value for the UV light, but the DiGeronimo reference, which is in the art of sterilizing packaging material, teaches irradiating at 254 nm (col.2, lines 50-52). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Kodera reference by irradiating at 254 nm as taught by the DiGeronimo reference since the lamp at such a wavelength operates at 99.9% efficiency (col.2, lines 50-52).

With respect to claim 25, the Kodera reference applies hot air (figure 1, 42 and 1) to the surface of the packaging sheet material without explicitly disclosing its temperature; however, the DiGeronimo reference, which is in the art of sterilizing packaging material, teaches applying an air stream of a temperature range value of between 150 to 155 degree Celsius (col.3, lines 13-14). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Kodera reference by drying the packaging sheet material with air heated to a temperature of 150 degree Celsius as taught by the DiGeronimo reference since such a modification is a matter of routine experimentation that depends on how the desired amount of hydrogen peroxide removal intended.

5. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kodera et al (U.S.P.N. 4,366,125) in view of DiGeronimo (U.S.P.N. 4,494,357) as applied to claim 21 and further in view of Lagunas-Solare et al (U.S.P.N. 5,364,645).

With respect to claim 6, both the Kodera reference and the DiGeronimo reference fail to disclose the use of polychromatic UV light source. The Lagunas-Solare reference, which is in the art of surface microbial disinfection, teaches that it is known to use Polychromatic UV light for surface microbial disinfection (col.1, lines 38-41). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify method of Kodera reference to include a polychromatic UV light source as taught by the Lagunas-Solare reference since such a source is known to be effective in surface microbial disinfection (col.1, lines 51-52 and lines 9-11).

6. Claims 18 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kodera et al (U.S.P.N. 4,366,125) in view of DiGeronimo (U.S.P.N. 4,494,357) as applied to claim 26 and further in view of Castberg et al (U.S.P.N. 5,744,094).

With respect to claims 18 and 27, both the Kodera reference and the DiGeronimo reference fail to disclose the use of an excimer lamp. The Castberg reference, which is in the art of sterilizing packaging materials using hydrogen peroxide and UV, discloses that it known to use an excimer lamp (col.2, lines 36-38). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Kodera reference to include an excimer lamp as disclosed by the Castberg reference since the geometry of the beam may be altered in response

to changes in fluid characteristics, i.e., aqueous hydrogen peroxide solution, in order to improve the efficiency of sterilization of wet surfaces (col.2, lines 34-38).

Response to Arguments

7. Applicant's arguments filed on 08/19/2005 have been fully considered but they are not persuasive.

On page 12 of the Remarks section, applicant argues that, "Prior to the present invention, it was not understood that the sequential steps claimed in the present application could function." Instant claims 4-5, 15, 21-23, 26 and 28 include the preamble "comprising" such that the order (sequential) of the steps does not limit the scope of the claims as long as those steps are known in the art.

On page 12 of the Remarks section, applicant argues that, "The prior art fails to recognize that even when hydrogen peroxide is removed from the packaging material, a residual or trace quantity of the hydrogen peroxide is absorbed or otherwise retained in or near the microorganisms, which is then available to react synergistically with the UV light." The Kodera reference applies a stream of air to the packaging sheet material for removing a substantial amount of hydrogen peroxide from the surface of the packaging material (col.5, lines 10-15). The specification only teaches of microorganisms without providing any significance. As a result, the microorganisms present on the surfaces of the packaging sheet material in the Kodera reference intrinsically absorb the residual hydrogen peroxide left after the step of drying. In addition, the Kodera reference teaches the importance of the synergistic effect produced by the combination of

hydrogen peroxide and UV (col.1, lines 13-18). Clearly the Kodera process provides for a trace quantity of hydrogen peroxide for its interaction with the UV light.

On page 13 of the Remarks section, applicant argues that, "even if the synergistic effect of hydrogen peroxide and UV light was well known, it was unobvious, and certainly not known to one of ordinary skill in the pertinent art, that the microorganisms were able to absorb hydrogen peroxide." The Kodera reference sterilizes sheets on whose surfaces microorganisms are present. See column 6, lines 5-8, where the Kodera reference teaches that Bacillus Subtilis spores are completely sterilized by the method. The absorption of hydrogen peroxide by Bacillus Subtilis spores is an intrinsic property of such spores. In addition, the specification only mentions microorganisms without providing any types of how such microorganisms would absorb hydrogen peroxide.

On page 15 of Remarks section, applicant argues that, "There is no suggestion in Kodera to locate the drying means upstream of the ultra-violet-ray sterilization means nor any other teaching that would lead one of ordinary skill in the art to practice the method claimed in claim 4, without hindsight of the present invention." Again, as mentioned above, instant claim 4 includes the preamble "comprising" such that the order (sequential) of the steps does not limit the scope of claim 4 as long as those steps are known in the art.

On page 16 of the Remarks section, applicant argues that, "That which may be inherent is not necessarily known. Obviousness cannot be predicted on what is unknown." The Kodera reference sterilizes sheets on whose surfaces microorganisms

are present. See column 6, lines 5-8, where the Kodera reference teaches that Bacillus Subtilis spores are completely sterilized by the method. Furthermore, the Kodera reference teaches the importance of the synergistic effect produced by the combination of hydrogen peroxide and UV (col.1, lines 13-18). The Kodera reference applies a stream of air to the packaging sheet material for removing a substantial amount of hydrogen peroxide from the surface of the packaging material (col.5, lines 10-15). Clearly the Kodera process provides for a trace quantity of hydrogen peroxide for its interaction with the UV light along with the microorganisms present.

On page 20 of the Remarks section, applicant argues that, "Contrary to the examiner's assertion, bath depth is not influenced by web thickness, but it is affected by web speed." The specification does not provide any significance to a bath with a depth of less than 50 cm. See pages 9 and 12 of the specification. Thus, absence of any advantage determining the proper depth of the immersion tank depends on the dimensions of the thickness of the packaging material, i.e., very thick laminates require a deeper bath. This is an obvious matter of choice of design within the scope of the artisan.

On page 23 of the Remarks section, applicant argues that, "The expression trace quantity is clearly used in the application to refer to a quantity present after drying and that is so small that it can even be absorbed by a microorganism, not a quantity that is several orders of magnitude greater such that it can be piped into and out of the sterilization chambers to form a thin film on the surfaces of the material to be sterilized in the manner taught by KODERA." The applicant refers to the means by which

hydrogen peroxide is generated in the Kodera apparatus; however, like the instant claims, the Kodera reference teaches applying a liquid solution of hydrogen peroxide to the surface of a packaging by immersing the material in a hydrogen peroxide bath (col.6, lines 25-28) then applying a stream of air the packaging sheet material for removing a substantial amount of hydrogen peroxide from the surface of the packaging material (col.5, lines 10-15). The specification does not provide specific meaning to "trace" other than being understood as small amount of hydrogen peroxide. Thus, both the instant claims and the Kodera reference leave a trace amount of hydrogen peroxide present on the packaging material.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

9. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 6:30-3:00.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JOHN KIM can be reached on (571) 272-1142. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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10/25/2005

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